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10/526,972	03/07/2005	Axel Brattstrom	26638U	7955

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EXAMINER	
CLARK, AMY LYNN	
ART UNIT	**PAPER NUMBER**
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/526,972	**Applicant(s)** BRATTSTROM, AXEL	
	Examiner Amy L. Clark	**Art Unit** 1655	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 March 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Michele C. Flood

MICHELE FLOOD
PRIMARY EXAMINER

Continuation of 11. does NOT place the application in condition for allowance because: The rejections are maintained for reasons of record set forth in the paper mailed on 1 December 2006 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 1 March 2007. Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.
Applicant argues that the test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. Richardson v. Suzuki Motor Co., 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. In re Bond, 15 USPQ2d 1566 (Fed. Cir. 1990). Applicant further argues that Claim 9 is directed to a medicament capable of substituting or complementing hormone replacement therapy, said medicament consisting at least in part of an extract obtained by concentration of an extract fluid from Cimicifuga racemosa in the presence of an effective amount of poly(vinylpyrrolidone) as a solvent mediator (Emphasis added by Applicant). Applicant further argues that in contrast, Houston et al. is directed to a composition and method for increasing the bioavailability of an aglycone in a subject, that the composition comprises at least two enzymes, for example, a xylanase, a glucanase, or a glucosidase. A method for converting a glycosylated isoflavone into an aglycone in a digestive tract of a subject, comprising orally administering an effective amount of a composition comprising at least two enzymes, for example, a xylanase, a beta-glucanase, or glucosidase, and concomitantly administering a food stuff, for example, glycolsylated isoflavone, and that Houston et al. does not teach a medicament consisting at least in part of an extract obtained by concentration of an extract fluid from Cimicifuga racemosa in the presence of an effective amount of poly(vinylpyrrolidone) as recited in present claim 9. Applicant further argues that in fact, Houston et al. teach an extract prepared in a conventional manner, i.e., "without the presence of polyvinylprrolidone (PVP) during extraction, acceding to Houston et al, PVP is added as an excipient to an "enzyme" which may be an extract obtained from black cohosh (cimicfuga), and that specifically, Houston et al. disclose:
In making the compositions of the present invention, the enzyme(s) can be mixed with a pharmaceutically acceptable excipient, diluted by the excipient or enclosed within such a carrier, which can be in the form of a capsule, sachet, paper or other container. Some examples of suitable excipients include lactose, dextrose, sucrose, sorbitol, mannitol, starches, gum acacia, calcium phosphate, alginates, tragacanth, gelatin, calcium silicate, microcrystalline cellulose, polyvinylpyrrolidone, cellulose, water, syrup and methyl cellulose (See Houston et al. at paragraph 83).
Applicant further argues that the extract taught in Houston et al. is not the same as presently claimed extract. Therefore, Applicant submit Houston et al. does not teach each and every element of the presently pending claim as required for anticipation under 35 U.S.C. § 102(a).
Applicant further argues that in the Official Action, the Examiner states:
...the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See the Official Action at page 4.
Applicant respectfully submits such a distinction can be gleaned from the present specification in Figures 1 and 2 and the corresponding explanation in Examples 3 and 4. More specifically, Applicant submits the specification provides clear proof that extracts according to the presently claimed subject matter, i.e., extracts prepared in the presence of PVP, are distinguishable form extracts produced by Conventional means, i.e., not in the presence of PVP.

Applicant further argues that the present specification clearly delineates the difference between the extract according to the presently claimed subject matter and that according to extracts produced by conventional means. For example the present specification discloses: Analytical results of three batches prepared according to example 1 gave the following triterpene glycoside values: 8.34%, 8.84% und 10.04% or an average of 9.07% corresponding to at least 6% if calculated as 27-deoxy acetein, the substance conventionally used for standardization of extracts of Cimicifuga racemos and that these values indicate a most desirable high concentration, notably when considering the fact that the final product contains about 25% of PVP. Applicant further argues that conventional extracts of Cimicifuga racemosa have a substantially lower content of triterpene glycosides and appear to be less effective at equivalent dosages and that the higher and apparently distinctive content of triterpene glycosides in an extract according to the invention is not due to an enrichment procedure but merely upon application of the method according to the invention providing for a recovery of active plant ingredients without loss. Applicant further argues that in vitro testing of Cimicifuga racemosa extract obtained according to the invention indicates binding to distinguishable somatic receptors as well as to receptors in the central nervous system so as to make such extracts a valuable candidate for alleviating climacteric and menopausal symptoms. (Emphasis added). See the present specification at page ii, lines 6-20 and, accordingly, Applicant submits the specification provides a clear indication an extract produced in the presence of PVP is a materially different extract than an extract produced in the absence of PVP. Specifically, as disclosed in the passage of the specification reproduced above, the extracts according to the presently claimed subject matter because conventional extracts of Cimicifuga racemosa have a substantially lower content of triterpene glycosides and appear to be less effective at equivalent dosages.
Applicant further argues that in further support of the patentability of the presently claimed subject matter, Applicant submits the skilled according to prior art compositions a skilled artisan would not have been lead to believe that presence of the prior art excipients, such as PVP, during extraction would significantly alter the composition of the extract, and, therefore, based on the prior art teachings a skilled artisan would expect a composition with a lower content of pharmaceutically active ingredients if the PVP added during production of the extract was allowed to remain in the extract. Applicant further argues that the presently claimed subject matter, as supported by the present specification, provides otherwise.

However, these arguments are not found persuasive because Houston teaches a pharmaceutical composition (which reads on medicament) comprising of an extract of black cohosh (See page 3, paragraph 0031), which is synonymous with Cimicifuga racemosa, and polyvinypyrrolidone (See page 7, paragraph 0083). Houston further teaches that black cohosh contains isoflavones, which are used to treat hot flashes in post-menopausal women (See page 1, paragraph 0009, continued onto page 2). Houston does not expressly teach that the composition is capable of being used as a substitute for or a compliment to hormone replacement therapy, however the

composition as taught by Houston is one in the same as that claimed by Applicant, therefore, the properties of the composition (as a substitute for or a compliment to hormone replacement therapy), as claimed by Applicant, are inherent to the composition taught by Houston. Although Houston does not expressly teach an extract obtained by concentration of an extract fluid from Cimicifuga racemosa in the presence of an effectie amount of poly(vinypyrrolidone) as a solvent mediator, it should be noted that Claim 9 constitutes a Product-by-Process type claim. In Product-by-Process type claims, the process of producing the product is given no patentable weight since it does not impart novelty to a product when the product is taught by the prior art. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983) and In re Brown, 173 USPQ 685 (CCPA 1972). Consequently, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product per se, even when limited to the particular process, is unpatentable over the same product taught in by the prior art. See In re King, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); In re Merz, 97 F.2d 599, 601, 38 USPQ 143-145 (CCPA 1938); In re Bergy, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) vacated 438 US 902 (1978); and United States v. Ciba-Geigy Corp., 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).
Therefore, the reference anticipates the claimed subject matter.

In response to Applicant's argument that the test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. Richardson v. Suzuki Motor Co., 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. In re Bond, 15 USPQ2d 1566 (Fed. Cir. 1990), that Claim 9 is directed to a medicament capable of substituting or complementing hormone replacement therapy, said medicament consisting at least in part of an extract obtained by concentration of an extract fluid from Cimicifuga racemosa in the presence of an effective amount of poly(vinylpyrrolidone) as a solvent mediator (Emphasis added by Applicant), that in contrast, Houston et al. is directed to a composition and method for increasing the bioavailability of an aglycone in a subject, that the composition comprises at least two enzymes, for example, a xylanase, a glucanase, or a glucosidase, amethod for converting a glycosylated isoflavone into an aglycone in a digestive tract of a subject, comprising orally administering an effective amount of a composition comprising at least two enzymes, for example, a xylanase, a beta-glucanase, or glucosidase, and concomitantly administering a food stuff, for example, glycolsylated isoflavone, that Houston et al. does not teach a medicament consisting at least in part of an extract obtained by concentration of an extract fluid from Cimicifuga racemosa in the presence of an effective amount of poly(vinylpyrrolidone) as recited in present claim 9, and that in fact, Houston et al. teach an extract prepared in a conventional manner, i.e., "without the presence of polyvinylprrolidone (PVP) during extraction, acceding to Houston et al, PVP is added as an excipient to an "enzyme" which may be an extract obtained from black cohosh (cimicfuga), and that specifically, Houston et al. disclose:
In making the compositions of the present invention, the enzyme(s) can be mixed with a pharmaceutically acceptable excipient, diluted by the excipient or enclosed within such a carrier, which can be in the form of a capsule, sachet, paper or other container. Some examples of suitable excipients include lactose, dextrose, sucrose, sorbitol, mannitol, starches, gum acacia, calcium phosphate, alginates, tragacanth, gelatin, calcium silicate, microcrystalline cellulose, polyvinylpyrrolidone, cellulose, water, syrup and methyl cellulose (See Houston et al. at paragraph 83).
Applicant further argues that the extract taught in Houston et al. is not the same as presently claimed extract, therefore, Applicant submit Houston et al. does not teach each and every element of the presently pending claim as required for anticipation under 35 U.S.C. § 102(a), please note the following. The way the claim is currently written, it appears that Applicant is claiming a medicament consisting at least in part an extract obtained by concentration of an extract fluid from Cimicifuga racemosa, which further comprises an effective amount of PVP poly(vinylpyrrolidone). The claims should be amended to indicate that extraction of Cimicifuga racemosa requires poly(vinylpyrrolidone). The claim does not indicate that PVP poly(vinylpyrrolidone) is necessary as part of the extraction process itself. Please note that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to Applicant's argument that in the Official Action, the Examiner states:
...the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See the Official Action at page 4.
Applicant respectfully submits such a distinction can be gleaned from the present specification in Figures 1 and 2 and the corresponding explanation in Examples 3 and 4. More specifically, Applicant submits the specification provides clear proof that extracts according to the presently claimed subject matter, i.e., extracts prepared in the presence of PVP, are distinguishable form extracts produced by Conventional means, i.e., not in the presence of PVP, that the present specification clearly delineates the difference between the extract according to the presently claimed subject matter and that according to extracts produced by conventional means. For example the present specification discloses:
Analytical results of three batches prepared according to example 1 gave the following triterpene glycoside values: 8.34%, 8.84% und 10.04% or an average of 9.07% corresponding to at least 6% if calculated as 27-deoxy acetein, the substance conventionally used for standardization of extracts of Cimicifuga racemos and that these values indicate a most desirable high concentration, notably when considering the fact that the final product contains about 25% of PVP, that conventional extracts of Cimicifuga racemosa have a substantially lower content of triterpene glycosides and appear to be less effective at equivalent dosages and that the higher and apparently distinctive content of triterpene glycosides in an extract according to the invention is not due to an enrichment procedure but merely upon application of the method according to the invention providing for a recovery of active plant ingredients without loss.
Applicant further argues that in vitro testing of Cimicifuga racemosa extract obtained according to the invention indicates binding to distinguishable somatic receptors as well as to receptors in the central nervous system so as to make such extracts a valuable candidate for alleviating climacteric and menopausal symptoms. (Emphasis added). See the present specification at page ii, lines 6-20 and, accordingly, Applicant submits the specification provides a clear indication an extract produced in the presence of PVP is a materially different extract than an extract produced in the absence of PVP. Specifically, as disclosed in the passage of the specification reproduced above, the extracts according to the presently claimed subject matter because conventional extracts of Cimicifuga racemosa have a substantially lower content of triterpene glycosides and appear to be less effective at equivalent dosages, that in further support of the

patentability of the presently claimed subject matter, and that the skilled according to prior art compositions a skilled artisan would not have been lead to believe that presence of the prior art excipients, such as PVP, during extraction would significantly alter the composition of the extract, and, therefore, based on the prior art teachings a skilled artisan would expect a composition with a lower content of pharmaceutically active ingredients if the PVP added during production of the extract was allowed to remain in the extract. Applicant further argues that the presently claimed subject matter, as supported by the present specification, provides otherwise., please note the following. Applicant has not claimed a specific extract from Cimicifuga racemosa, nor has Applicant claimed the percentages of the components extracted from Cimicifuga racemosa. Therefore, the medicament taught by Houston is one and the same as the medicament claimed by Applicant. Please also note that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).